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Stockpiled N95 respirator/surgical mask release beyond manufacturer-designated shelf-life: a French experience

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SUMMARY

Background: To reduce the shortage of N95 respirators and surgical masks during the COVID-19 pandemic, stockpiled equipment beyond its expiry date could be released. **Aim:** Centralized testing of batches of expired surgical masks and N95 for safe distribution to hospital departments saving users time.

Methods: Tests of compliance with health authority directives were developed and carried out on 175 batches of N95 masks and 31 batches of surgical masks from 12th March 2020 to 16 April 2020. Five quality-control tests were performed on batch samples to check: packaging integrity, mask appearance, breaking strength of elastic ties and strength of nose clip test, and face-fit.

Findings: Forty-nine per cent of FFP2 mask batches were compliant with directives, 32% of batches were compliant but with some concerns and 19% of batches were non-compliant. For surgical masks, 58% of batches were compliant, 39% of batches compliant but with concerns and 3% of batches were non-compliant.

Conclusion: The main areas of non-compliance were the breaking strength of the elastic ties and the nose clip but these alone were not considered to make the masks unacceptable. Only mask appearance and face-fit results were decisive non-compliance criteria.

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Introduction

The risk of pathogen transmission can be reduced by using a disposable filter respiratory protection against particles and

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aerosols [1]. There are several types of single-use masks providing different levels of protection. Surgical masks stop at least 80% of aerosols and protect the people around the user. N95 filtering facepiece respirators (American equivalent of European FFP2 masks) stop at least 94% of aerosols and protect the wearer against infections. However, the COVID-19 pandemic has led to a drastic shortage of personal protective equipment worldwide [2].

Table 1

Quality control results on FFP2 and surgical masks stockpiled beyond their expiry date

		FFP2 mask batch (n = 175)		Surgical mask batch (n = 31)	
Absolute compliance: n (%)		85 (49)		18 (58)	
Compliance with reservation: n (%)		57 (32)		12 (39)	
Absolute non-compliance: n (%)		33 (19)		1 (3)	
Non-compliance: N (%)	Packaging integrity	2 (1) ^a		0 (0)	
	Mask appearance	12 (7)		1 (3)	
Breaking strength of the elastic ties	1–3 samples	30 (17)	65 (37)	3 (10)	12 (39)
	4–6 samples	13 (7)		2 (6)	
	7–9 samples	22 (13)		7 (23)	
Strength of the nose clip		15 (9)		0 (0)	
Face fit		28 (16)			
Batch with 1 non-compliance		66 (38)		13 (42)	
Batch with 2 non-compliances		18 (10)		0 (0)	
Batch with 3 non-compliances		7 (4)		0 (0)	

^a 36% of packaging was missing.

Following the H1N1 influenza epidemic health crisis in 2009, France constituted a safety stock of one billion surgical masks and of 799.9 million FFP2 masks (equivalent to N95). In 2013, there was a change of approach to stock management which was found to be too expensive. The new management approach generated a shortage of surgical and FFP2 masks in hospitals right from the beginning of the COVID-19 health crisis, exposing caregivers to the highest risk of contamination.

Driven by the urgent need for masks to prevent the spread of COVID-19, stockpiled FFP2/N95 and surgical masks that had passed their manufacturer-designated shelf-life were released. Given the prevailing emergency, the usual standards for the control of medical devices were adapted to the financial and material resources available.

In the USA, the Center for Disease Control and Prevention (CDC) published recommendations [3] stating that prior to using the respirator in the workplace, users should take four precautionary measures: three visual tests, and one user seal check. CDC is also currently conducting a study to evaluate stockpiled N95 from several geographically scattered facilities.

In France, the release of expired batches of FFP2/N95 and surgical masks was the responsibility of the Agence Régionale de Santé (ARS, the regional public authority responsible for the implementation of health policy in a given region). According to French Health Ministry directives [4], four verifications, similar to the CDC tests, were required on the FFP2 mask batches before release: packaging integrity verification, mask appearance verification, breaking strength test on elastic ties and strength test on nose clip, and face-fit test. These tests, contrary to CDC recommendations, were not to be performed by the users. Ministerial directives recommended that health structures use existing resources such as quality-control laboratories to perform the tests.

Our laboratory was commissioned by the ARS of Provence Alpes Côte d'Azur region to develop and apply a protocol of the various assessments of compliance with standards for the expired batches of masks.

Materials and Methods

Between 12th March 2020 and 16th April 2020, 175 batches of FFP2/N95 masks and 31 batches of surgical masks were checked. Batches were sent from 12 different establishments and produced by 42 different companies. The mask expiry dates varied from 2001 (the oldest) to October 2018 (the most recent). There was no expiry date for 25% of FFP2/N95 mask batches and 45% of surgical mask batches.

From each batch, a sample of 15 FFP2/N95 masks and 12 surgical masks was taken for testing. Some samples were used for several tests. Except for the face-fit test performed only on three FFP2/N95 masks by batch, identical testing was carried out on both types of masks. For each batch, three masks were kept stored in the laboratory.

The primary and secondary producers' packaging integrity was visually verified, searching in particular for alterations (discoloration, cracks, moisture, tears) in the packaging. For each batch, 10 samples were checked when possible.

Mask appearance verification was inspected visually under an inspection machine with black and white background. A check for deterioration (discoloration, tears, decomposition) was carried out on 10 samples which could then be used for other tests.

The breaking strength of the elastic ties was evaluated with an Instron 3343 dynamometer and strength transducer (INSTRON 02062 Massachusetts, USA) with a capacity of 100 N. The apparatus was connected to a DELL Optiplex GX520 computer equipped with data processing software (Bluehill). The mask was placed between fixed jaws of the dynamometer and the elastic ties between movable jaws. Elastic strain was applied at a speed of 500 mm/min, as soon as an elastic broke under the extension, a measurement was recorded and the breakage site noted. Before each measurement set, three reference masks (from valid batches) were tested. The compliance limit was the lowest value reduced by 10% from a reference measurement set. For each batch, nine samples were checked.

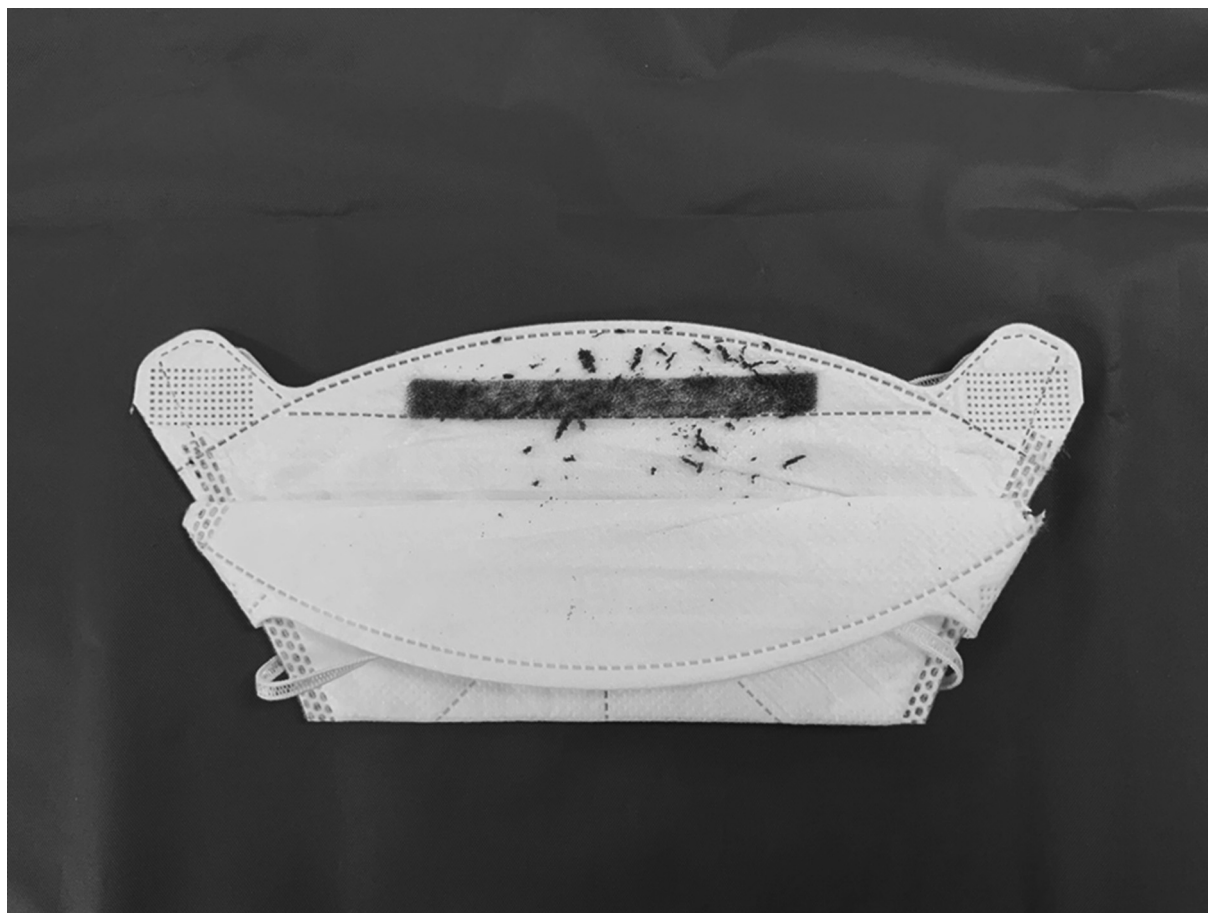


Figure 1. Defective internal nose foam.

The strength of the nose clip was tested manually by performing 10 twists along the full length of the clip. The same nine samples were checked for the elastic tie breaking strength test, and a valid reference mask was tested per batch.

The face-fit test was performed using three ultrasonic nebulizers (model 1: SYSTAM LS290; model 2: Shinmed SW966 ORKYN; model 3: Europe Medical NU52). A sodium saccharin (Cooper 7700 Melun, France) solution was employed for control. This test followed an adapted ED 6273 protocol [5] from the Institut National de Recherche et de Sécurité (INRS: reference organization in occupational health and risk prevention in France) relating to breathing protection. The ultrasonic nebulizer was filled with 8 mL of a 415-g/L sodium saccharin solution. The experimenter was placed in an airtight environment with a plastic bag, covering his upper body and the nebulizer hose placed nearby, within this environment. The breathing exercises performed by the experimenter consisted of 1 min of normal breathing, 1 min of deep breathing, 30 s of head movements from right to left, 30 s of head movements from top to bottom and 1 min of talking. A 10-s nebulization of the sodium saccharin solution was performed at 1-min intervals. Each exercise set ended with a positive control, where the experimenter removed the mask in the airtight environment. Compliance was validated if experimenter did not experience any sweet taste while wearing the mask but experienced a sweet taste during the positive control. For

each batch, three independent experimenters tested one mask each.

Results

Forty-nine per cent of FFP2/N95 mask batches were compliant according to the different tests, 32% of batches were compliant with concerns and 19% of batches were non-compliant with the ministerial directive (Table 1). Non-compliance was based on various factions: packaging integrity (1% of batches), visual appearance (7% of batches), breaking of the elastic ties (37% of batches), breaking of the nose clip (9% of batches), and fit problems (16% of batches). The decisive criteria for batch non-compliance were both the appearance and the face fit. The concerns expressed for 32% of compliant batches relate to the fragility of the elastic ties and the nose clip. For surgical masks, 58% of batches were found to be compliant, 39% of batches compliant but with concerns about the fragility of the elastic ties and 3% of batches non-compliant.

The primary and secondary packaging verifications did not reveal non-compliance with the ministerial directives, except for 1% of FFP2 mask batches. However, 36% of batches from different establishments and different producers were not sent in their secondary packaging, but simply placed in plastic bags, still in their primary packaging. Thus, it cannot be concluded

that primary and secondary packing criteria were fulfilled. Moreover, primary packaging differed from one manufacturer to another: some manufacturers packaged their masks in individual plastic bags, others in batches of 20 units per plastic bag or 50 units per cardboard box.

The visual inspection of masks revealed a non-compliance with the ministerial directives for 7% of FFP2 mask batches and 3% of surgical mask batches. In the majority of these batches, the nose foam crumbled easily when touched (Figure 1). At the establishment's request, compliance testing on its batches stopped when this result was obtained. Another establishment asked us to cover the foam with adhesive tape and to continue testing. One batch from a donation to a hospital was suspected of being counterfeit. An N95 mask has to carry a brand name, a National Institute for Occupational Safety and Health (NIOSH) logo, a TC approval number, a filter class and filter efficiency level and a model number [6]. On the suspect batch, all the required data except the NIOSH logo and the filter class and efficiency level were missing (Figure 2). The face-fit test was also negative for this batch.

The breaking strength test of the elastic ties showed that 63% of the FFP2/N95 mask batches were compliant and 37% were non-compliant with the ministerial directives. Among the non-compliant batches, there were three categories: 17% of batches with one to three non-compliant samples, 7% of batches with four to six non-compliant samples and 13% of batches with seven to nine non-compliant samples (Table 1).

Two different break points were observed and noted: junction point between elastic and mask, and middle of elastic. For the surgical masks, this test revealed non-compliance with the ministerial directives: there were 10% of batches with one to three non-compliant samples, 6% of batches with four to six non-compliant samples and 23% of batches with seven to nine non-compliant samples.

The strength test on the nose clip test revealed that 9% of batches were non-compliant with the ministerial directives: either the nose clip broke from the first twists, or the nose clip broke during the last twists. Moreover, 2% of the batches had no nose clip and therefore were not checked for this criterion.

On the face-fit test, 16% batches were non-compliant with the ministerial directives. Batches were considered non-compliant as soon as the experimenter experienced a sweet taste during at least one exercise of the test. For 1% of the batches, a fourth experimenter performed the test to avoid errors.

Discussion

Since the beginning of the COVID-19 health crisis, there has been a dramatic shortage of surgical and FFP2/N95 masks, leaving health caregivers exposed to a high risk of infection. The French Health Ministry sent directives to hospitals, instructing them to test masks whose expiry date had passed and to extend their use. In response to these directives, our



Figure 2. Possibly counterfeit N95 mask.

laboratory specially designed several tests and adapted INRS guidelines [5] for the face-fit test.

Of the 206 batches assessed, 81% of FFP2/N95 mask batches and 97% of surgical mask batches were found sufficiently compliant with the ministerial directives. Most cases of non-compliance involved the nose clip and elastic ties, but were not considered to preclude use. However, non-compliance involving the face-fit could lead to contamination, non-compliance involving mask appearance would indicate poor state of preservation.

The test on elastic tie to breaking strength yielded three categories of batches. Batches containing one to three non-compliant samples needed to be considered fragile in terms of their elastic ties. Batches containing four to six non-compliant samples warranted precautionary measures. Batches containing seven to nine non-compliant samples were not recommended for use. Nevertheless, depending on the breaking point of the elastic, establishments may still be able to use the mask: if the breaking point is at the junction between the elastic and the mask, the mask can be used provided this point is reinforced with staples.

In addition to revealing batches that were insufficiently airtight, the face-fit test revealed other characteristics that could make them unsatisfactory. Some batches had strong musty odours or strong chemical odours which could indicate poor storage conditions. One batch had very poor breathability, preventing its use.

Given the health emergency represented by this crisis, a compromise had to be made between performing lengthy tests to the usual standards and the speed to obtain rapid results. To avoid cases such as that of Reunion Island, where masks appearing moldy were delivered to hospitals, meticulous testing must be applied. In our laboratory, although utmost care was given to all tests, each result was obtained within 6 working hours.

The fact that all testing required by the ministerial directives was grouped together in the same laboratory provided a comprehensive picture. This made it possible to quickly identify the various non-compliances that commonly arose, but also to check masks donated to hospitals, the origin of which could not always be verified. Thus, counterfeit masks were quickly suspected, then confirmed by the absence of regulatory data.

Because of the lack of comprehensive guidelines for assessing the quality and efficiency of these masks, the Health Ministry published its two directives with low requirements in a crisis context. It would be wise to take advantage of this experience to create a national standard protocol that would harmonize quality controls by different laboratories and enhance the rapid response to such testing accords in a health crisis. The Ministry should also take advantage of this critical situation to modify the national stock management policy in two directions: by increasing safety stocks as well as production autonomy to reduce worldwide dependence in one manufactory country. This would avoid recourse to inadequate solutions appearing during health crises, such as manufacturing paper or cloth masks, not officially recommended for use due to scientific evidence that they do not protect against viral contamination [7,8].

This work has several limitations. First, the urgency of the health situation forced this study to be conducted over a short period of time. Moreover, during the epidemic, there was a lack of material and time needed to control mask conformity with

regards to standards. To our knowledge, mask quality control in an emergency context has not been described before and required the development of new techniques. The protocol we described can not guarantee compliance to standards but allows the detection of critical non-compliance.

The COVID-19 health crisis led to a shortage of respiratory protection masks but also of all personal protective equipment. The development of emergency quality control protocols for equipment such as gloves or overcoats would allow the rapid release of expired batches. Beyond this epidemic, quality control protocols could also allow the rapid identification of counterfeit protective equipment.

Of the 175 batches of FFP2/N95 masks and 31 batches of surgical masks tested by our laboratory in 36 days, 81% of FFP2 mask batches and 97% of surgical mask batches were released for use. The testing prevented 19% of defective batches of FFP2/N95 masks and 3% of defective batches of surgical masks being delivered to healthcare personnel. Even in a health crisis context, it is vital to take the time to perform the quality checks that guarantee the safety of personnel.

Under the conditions of extreme tension and lack of time experienced by hospital staff in contact with COVID-19 patients, the quality control of stockpiled N95 respirators and surgical masks should not be verified by the users themselves. Pharmaceutical expertise, for example from quality control laboratories, can help relieve healthcare workers of these verifications and can detect defective masks.

Conflict of interest statement

None.

Funding sources

None.

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